

MAY - 8 2012

**5. 510(k) Summary****21 CFR 807.92(a)(1): Submitter and Manufacturing site information**

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**Establishment registration number:** 3003793891**Date of the present summary preparation:** 28<sup>th</sup> December, 2011**21 CFR 807.92(a)(2): Device information**

<b>Trade name</b>	PERFORMER HT / HANG&GO HT BASIC
<b>Device Classification Name</b>	Warmer, thermal, infusion fluid
<b>Classification Review Panel</b>	General Hospital
<b>Classification Product Code</b>	LGZ
<b>Regulatory Class</b>	Unclassified, pre-amendment device

**21 CFR 807.92(a)(3): Predicate devices**

The PERFORMER HT is substantially equivalent to the Belmont Hyperthermia Pump (K070654, dtd June 8<sup>th</sup>, 2007).

**21 CFR 807.92(a)(4): Description of the device**

The PERFORMER HT is a prescription electromechanical device intended to provide isolated hyperthermic perfusion in the thoracic or peritoneal cavity by means of extracorporeal circulation of warmed, physiologically compatible sterile solution.

The PERFORMER HT equipment is designed to:

- operate the treatment execution by means of a color touch-screen display
- control the temperature of solution perfused to the Patient through the extracorporeal circuit
- control the flow rates of roller pumps
- control the volume in the extracorporeal circuit and Patient's body cavity
- monitor Patient's body cavity temperatures
- monitor the extracorporeal circuit pressures
- detect air in the circuit
- change the fluid path in the extracorporeal circuit by means of 2 two-ways pinch valves

The Central Information Display (CID) enables the User to interact with the PERFORMER HT equipment. The touch-screen display allows the User to:

- input Patient information
- operate the various treatment phases
- display treatment parameters (e.g, flows, pressures, temperatures)
- set treatment parameters
- set alarm limits
- display graphical trending of temperature probes connected to the HTS module

- read alarm and alert messages

The PERFORMER HT is intended to be used with the HANG&GO HT BASIC, a disposable, single use kit intended to circulate and filtrate the clear solutions in the thoracic or abdominal cavity.

The HANG&GO HT BASIC includes all necessary lines and accessories for the treatment execution:

- circulation line
- heater bag
- reservoir
- table pack (Patient inlet and outlet lines) with thermal protections

The HANG&GO HT BASIC is supplied sterile, packaged in a proprietary-design container, and is intended to be used only with the PERFORMER HT.

#### **21 CFR 807.92(a)(5): Intended use**

The intended use of the PERFORMER HT is to provide isolated hyperthermic perfusion in the thoracic or peritoneal cavity by means of extra-corporeal circulation of warmed, physiologically compatible sterile solution, according to a protocol to be selected by the physician.

The device must be used by a qualified medical professional who is experienced in the operation of this or similar equipment.

#### *Predicate device intended use*

The intended use of the Belmont Hyperthermia Pump is to raise the temperature of the thoracic or peritoneal cavity to the desired target temperature by continuously lavaging the cavity with circulating warmed sterile solution, according to a protocol to be selected by the physician.

#### **21 CFR 807.92(a)(6): Comparison of technological characteristics**

The PERFORMER HT has the same operating principle, energy type, environmental specifications, and performance specifications of the Belmont device. It uses roller-type fluid pumps, touch screen to direct the User through set-up preparation and use, control and monitoring of fluid temperatures, and a proprietary-design disposable set including large fluid reservoir to circulate sterile fluid into and out of the body cavity. Flow from the reservoir is delivered by action of the roller pump to the heater exchanger to be heated to the desired target temperature, and then to the Patient. From the Patient, the fluid is pumped from the return line back into the reservoir. The PERFORMER HT monitors circulating flow, temperatures, pressures and volumes, detects air in the circuit and automatically responds to ineffective or unsafe operating conditions by sounding audible alarms, stopping heating and pumping in case of hazardous conditions for User/Patient.

**21 CFR 807.92(b)(1): Discussion of the non-clinical tests**

The PERFORMER HT is designed to, complies with, and has been tested to, the FDA Recognized Consensus Standards listed in the table below, as applicable to the equipment, the disposable lines set and the components:

**Table 1: Applicable Reference Standards list**

Area	US Recognized standard #	EU Recognized standard #	Title
General		EN ISO 13485:2003 / AC:2007	Medical devices -- Quality management systems -- Requirements for regulatory purposes
	ISO 14971:2007	EN ISO 14971:2007	Medical devices - Application of risk management to medical devices
Packaging and labeling		EN 980:2008	Symbols for use in the labelling of medical devices
		EN 1041:2008	Information supplied by the manufacturer with medical devices
		ASTM D4169-04a	Standard Practice for Performance Testing of Shipping Containers and Systems
Biocompatibility	AAMI ANSI ISO 10993-1:2009	EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing
		EN ISO 10993-4:2002	Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood
	AAMI ANSI ISO 10993-5:2009	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity
	AAMI ANSI ISO 10993-7:2008	EN ISO 10993-7:2009	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
	ISO 10993-10:2002/Amd 1:2006	EN ISO 10993-10:2002/Amd 1:2006	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
	AAMI ANSI ISO 10993-11:2006	EN ISO 10993-11:2006	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
Electrical safety	IEC 60601-1:1988/Amd 1:1991 & Amd 2:1995	EN 60601-1:1990/Amd 1:1993 & Amd 2:1995	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
	IEC 60601-1-1:2000	EN 60601-1-1:2001	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
	AAMI ANSI IEC 60601-1-2:2001	EN 60601-1-2:2001	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
	IEC 60601-1-4:2000	EN 60601-1-4:1996/Amd 1:1999	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
		EN 60601-1-6:2004	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
Sterility	AAMI ANSI ISO 11135-1:2007	EN ISO 11135-1:2007	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
	AAMI ANSI ISO 11607-1:2006	EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

	AAMI ANSI ISO 11607-2:2006	EN ISO 11607-2:2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
	ASTM F1980-07		Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
	AAMI ANSI ISO 11737-1:2006	EN ISO 11737-1:2006	Sterilization of medical devices- Microbiological methods-Part 1: Determination of the population of microorganisms on product
Human factors	IEC 62366:2007	EN 62366:2008	Medical devices - Application of usability engineering to medical devices
Software	IEC 62304:2006	EN 62304:2006	Medical device software - Software life cycle processes

Tests were carried out on the PERFORMER HT system (equipment and disposable) to assess:

- The ability of the system to heat and pump fluids accurately over the full range of flow rate and operating conditions;
- The ability of the system to maintain fluid temperature over the full range of fluid flow rates;
- The ability of the system to control the pressures, volumes and flow rate accuracy over the full range of fluid flow rate within the operating temperature and pressure range;
- The ability of the system to detect and alarm at unsafe or ineffective operating conditions including operator errors, the failure of the system sensors, and other internal system malfunctions;
- The ability of the system to mitigate against known or predictable operator errors;
- The ability of the system to store parameters and data in non-volatile memory.

The PERFORMER HT performed within the specifications in all of the above tests.

### **Software verification and validation**

PERFORMER HT software ability to meet performance specifications has been verified through the tests described above. Software control of all functions, actuators and parameters has been verified at unit, integration and system level.

### **Human Factors**

A human factors non-clinical study was conducted in a simulated use environment with the purpose to optimize the system's user interface through human factors analysis, testing and validation. The study evaluated user- and patient-safety risks associated with the design of the PERFORMER HT system and demonstrated that the task-risks and errors that occur during use of the device have been identified, addressed and either eliminated or reduced.

### **21 CFR 807.92(b) (3): Conclusions**

Based upon safety and performance testing and compliance with voluntary standards, RanD believes that the PERFORMER HT is substantially equivalent to the predicate device, and does not raise any new questions of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
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Ms. Simone Ceretti  
Regulatory Affairs  
RanD S.r.l.  
Via Statle 12, 62  
MEDOLLA  
ITALY 41036

MAY - 8 2012

Re: K120026  
Trade/Device Name: PERFORMER HT System  
Regulation Number: Unclassified  
Regulation Name: Thermal Fluid Warmer  
Regulatory Class: II  
Product Code: LGZ  
Dated: April 24, 2012  
Received: April 26, 2012

Dear Ms. Ceretti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOoffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

#### 4. Indications for Use Statement

510(k) Number (if known): none

Device Name: PERFORMER HT system

Indications for Use:

The intended use of the PERFORMER HT is to provide isolated hyperthermic perfusion in the thoracic or peritoneal cavity by means of extra-corporeal circulation of warmed, physiologically compatible sterile solution, according to a protocol to be selected by the physician.

The device must be used by a qualified medical professional who is experienced in the operation of this or similar equipment.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  R. L. C. Chp   5/8/12  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number:   K120026